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Japan's New Food Safety Basic Law 2003

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Report Highlights: The proposed Food Safety Basic Law, as recently approved by Japan's House of Representatives, sets the principles for developing a food safety regime including the establishment of the Food Safety Commission. In most cases, the draft should result in few specific changes on how imports will be handled. However, tighter border inspections can be expected and the law has vague language concerning traceability as well as the possible use of the precautionary principle. The draft has now been passed to the House of Councilors (HOC) for deliberation and should go into effect this summer.

Includes PSD Changes: No
Includes Trade Matrix: No
Unscheduled Report
Tokyo [JA1]
[JA]

Japan's Food Safety Basic Law

The Japanese government is in the process of revising its basic food safety laws in order to regain consumer confidence following the BSE outbreak in 2001 and numerous subsequent food mislabeling and food safety issues. The Food Safety Basic Law was passed by the House of Representatives (HOR) on April 22nd and has now been passed to the House of Councilors (HOC) for deliberation. However, few major changes are expected from these continued discussions and the law is expected to take effect by summer of 2003.

The law provides the basic principles and parameters for Japan's food safety regime and administration based on major points:

- Assurance of food safety
 - Consumer-first
 - Science-based risk assessment
 - From farm to table (traceability)
- Local government and consumer involvement
 - Food related businesses to have primary responsibility for assuring food safety
 - Consumers are to be educated and involved in the policy making process
- Coordinated policy guidelines
 - Risk assessment to be done prior to policy decisions
 - The necessity for crisis management and preventative measures is emphasized
 - Risk assessors and risk managers are to coordinate actions
 - Risk communication is promoted
- Establishment of the Food Safety Commission (FSC)
 - The FSC is to be established as a Cabinet Office reporting directly to Prime Minister.
 - The FSC will perform independent risk assessments and provide science-based advice to risk managers i.e. Ministry of Agriculture, Forestry and Fisheries and the Ministry of Health, Labor and Welfare. (Please refer to Gain Report JA#3001 for detail.)

A summary of the draft law is attached to this report. In most cases, the law, as currently drafted, will probably result in few specific changes for how imports will be handled in the future. However, tighter border inspections can be expected and the law has vague language that could lead to the requirement of some form of traceability as well allowing the possible use of the precautionary principle. These potential areas of concern are discussed below and a rough summary of the draft law follows.

1. Food chain safety assurances required for imported as well as domestic food.

Chapter 1 – Article 4. In last minute deliberations, the HOR changed the text regarding assurance of food safety at every stage of food supply chain from “domestic” to “domestic and foreign”. While the GOJ cannot require exporting countries to follow identical procedures to those mandated in Japan, this change can be expected to result in increased scrutiny of imported products and importers may begin calling for additional documentation from suppliers.

In addition, the Supplementary Resolutions in the draft law specifically call for the promotion of traceability by the government. Although the Supplemental Resolutions do not have any legally binding authority, they do set the tone for any subsequent implementing legislation.

NOTE: A separate bill is currently under deliberation in the HOR for beef traceability. This bill, which is expected to pass soon, will mandate the use of a 10-digit code for tracking feed

and location records for domestic beef from farm to table. As in the case with the Food Safety Basic Law, this beef traceability law will not give the GOJ the authority to regulate imported beef. It is expected that export certificates currently being used will suffice for BSE-free countries. Post will follow the progression of these regulations carefully in the months to come. END NOTE.

2. Precautionary import bans allowed.

Chapter 2 – Article 11 says that (bans on imports) in the case of food safety related emergencies may be enacted prior to a risk assessment being done by the FSC.

Precautionary measures are also mentioned in Chapter 2 – Article 14 which says, *“Necessary measures must be taken to prepare a system to cope with damages and subsequent emergencies, and prevent such emergencies so that serious food borne health damages can be prevented.”*

However, it should be noted that the document also calls for taking a science-based approach in risk assessments in general, and requires that a risk assessment be done as soon as possible in the event of emergency actions.

The Food Safety Basic Law

Abridged provisional translation

Chapter 1 General Provisions (Articles 1 – 10)

(Purpose)

Article 1 The purpose of this law is to promote measures relating to the assurance of food safety in a comprehensive manner in consideration of the urgent necessity to cope with such changes surrounding citizens' eating habits as advances in technology and internationalization. This shall be done by establishing the basic principles of food safety and clarifying the responsibilities of the state, local public entities and food related business entities as well as the role of consumers.

(Definition)

Article 2 In this Law, "Food" refers to all foods and beverages (except ones defined as pharmaceuticals and quasi-pharmaceuticals under the Pharmaceutical Law).

(Basic principle)

Article 3 Measures necessary for assuring food safety must be implemented based on the recognition that protection of the consumers' health is of utmost importance.

(Appropriate measures at each level of food supply chain)

Article 4 Recognizing that food safety is affected by every factor in the food chain, both domestic and foreign and from production to sales, food safety must be assured by taking the appropriate and necessary measures at each level of the food supply chain.

(Prevention of adverse health affects)

Article 5 Measures necessary for assuring food safety must be implemented for the purpose of preventing any adverse health affects to consumers. Such measures must be based on scientific knowledge and with sufficient consideration of international information and experience as well as the opinion's of Japanese consumers.

(Responsibility of the state)

Article 6 The state shall be responsible for making and implementing such measures relating to the assurance of food safety in a comprehensive manner, in line with the basic principle stipulated in Article 3, hereinafter referred to as "the basic principle".

(Responsibility of local government)

Article 7 Based on the basic principle, local governments shall be responsible for making and implementing the necessary measures for the assurance of food safety in their regions in response to each region's natural and economic conditions, and with an appropriate division of roles between their office and the state.

(Responsibility of food related businesses)

Article 8 Recognizing that they hold the primary responsibility in assuring food safety, manufacturers, importers, sellers and other related businesses, hereinafter referred to as "food related businesses", involved in fertilizers, agricultural chemicals, feed, feed additives, animal drugs and other agricultural/fishery

materials that potentially affect safety of food, food (including those used as ingredients), additives, instruments, and packages shall be responsible for implementing the measures necessary to assure food safety at each stage of the food supply chain in an appropriate manner, based on the basic principle,.

(Role of consumers)

Article 9 Consumers are to play an active role in the assurance of food safety by expressing their opinions on the related measures and expanding their knowledge and understanding of food safety.

(Legislative measures, etc.)

Article 10 The government must take the legislative, budgetary and other measures necessary for implementing measures to assure food safety.

Chapter 2 Basic Guidelines for Policy Making (Articles 11 – 21)

(Assessment of the affect on health)

Article 11 1. When taking measures related to food safety, an assessment, hereinafter referred to as "health impact assessment", must be made for each measure on its impact on human health. The assessment should include a review of any substances in their biological, chemical or physical factor or state that are contained in the food or that come in contact with the food (package) and which may have a potential harmful impact on the human health of the consumers.

However, this shall not apply in the following cases:

- i. When it is clear that the subject measure does not require a health impact assessment.
 - ii. When the harmful impact and its degree of impact on human health are clear.
 - iii. When the an action must be taken quickly in order to prevent or cub the harmful impact on human health and there is not time available for a prior health impact assessment.
2. For iii above, the health impact assessment must be made ex post facto without delay.
3. The health impact assessment must be made using the highest level of science currently available and in an objective and unbiased manner.

(Health impact assessment in relation to eating habits.)

Article 12 Measures relating to food safety must take into consideration such matters as the consumers' eating habits in order to prevent or curb the potential harmful impact on human health. When a health impact assessment is conducted as required in the previous article, the measure(s) must be based on the result of the assessment.

(Promotion of information/opinion exchange)

Article 13 Measures must be taken to provide consumers the opportunity to express their opinions as well as to promote the exchange of information and opinions between the parties involved in order to ensure fairness and transparency in

regard to actions taken and that the consumers' opinions are reflected in the actions taken.

(Emergency action system)

Article 14 Necessary measures must be taken to prepare a system to cope with potential damages and subsequent emergencies, and to prevent such emergencies in order to avoid serious food borne health risks.

(Close coordination/collaboration between related administrative organizations)

Article 15 The relative administrative organizations must closely coordinate their actions so that appropriate measures are taken at each level of food supply chain in order to assure food safety.

(Preparation of research and testing system)

Article 16 Since the enhancement of scientific expertise is important for assuring food safety, necessary measures must be taken to prepare a research and testing system, to promote research and development, to diffuse the result of research and development, and to nurture researchers.

(Collection, sorting and utilization of information, domestically and internationally)

Article 17 Necessary measures must be taken to collect, sort and utilize domestic as well as international information relating to food safety assurance in order to implement appropriate and effective food safety assurance measures that take into account changing conditions such as the eating habits,

(Assurance of appropriate application of labeling system)

Article 18 Considering that food labeling plays an important role in assuring food safety, necessary measures must be taken to assure the application of an appropriate food labeling system that accurately conveys relevant information.

(Education and learning relating to food safety assurance)

Article 19 Necessary measures must be taken to deepen the consumers' knowledge and understanding of food safety measures by promoting food safety education/learning and enhancing public relation activities.

(Consideration to the impact on environment)

Article 20 Measures relating to food safety assurance must take into account the impact of the subject measures on the environment.

(Decision and public notification of fundamental matters pertaining to the implementation of measures)

Article 21

1. The government must establish fundamental matters, hereinafter referred to as the "fundamentals," pertaining to the measures to be taken based on Article 11 through 20.
2. Based on opinions of the Food Safety Commission, The Prime Minister must draft the fundamentals, and then seek their approval by the Cabinet.
3. The Prime Minister must, without delay, publicly announce the fundamentals upon approval by the Cabinet.

4. When changes are made in the fundamentals, procedures in the preceding two clauses shall apply.

Chapter 3 Food Safety Commission (Article 22 – 38)

(Establishment of the Commission)

Article 22 The Food Safety Commission (hereinafter referred to as the Commission) shall be established in the Cabinet Office.

(Duties to be carried out)

Article 23

1. The Commission shall administer the following duties:

- i. Give opinions to Prime Minister as set in Article 21-2.
- ii. Conduct health impact assessment as set in the following Article.
- iii. Based on the result of the health impact assessment, provide advice regarding measures to be taken for food safety assurance to the related Ministers, through the Prime Minister, as set in the above sub-clause (Article 23-1-iii).
- iv. Monitor the status of the implementation of the measures implemented based on the health impact assessment conducted as called for in sub-clause ii above, and give advice, as deemed necessary, to related Ministers through the Prime Minister.
- v. Examine and deliberate matters of importance regarding the measures that should be taken for the purpose of food safety assurance and give opinions, as deemed necessary, to the heads of related administrative organizations.
- vi. Conduct scientific research and studies necessary to fulfill the duties described in the above ii-v.
- vii. Plan and implement measures to allow the exchange of information and opinions between the parties involved in duties ii-vi above.
- viii. Coordinate the work done by related administrative organizations through an exchange of information/opinions between the parties involved in food safety assurance.

2. The Commission must, without delay, notify related Ministers of the result of the health impact assessment based on the above Clause 1-ii.
3. The Commission must publicly announce, without delay, the content of the notifications made under the above Clause 2 or the advisories made under the above Clause 1-iii or iv.
4. Each related Minister must report to the Commission on the measures taken in response to the advisories made under the above Clause 1-iii or iv.

Article 24 (translation omitted)

Article 25 (translation omitted)

Article 26 (translation omitted)

Article 27 (translation omitted)

(Organization)

Article 28 The Commission shall consist of seven (7) members, three (3) of whom shall be part-time members.

(Appointment of Commission members)

Article 29 Members shall be; chosen from those who have outstanding knowledge of food safety assurance; approved by both Houses; and appointed by Prime Minister.

(Term of service by Commission members)

Article 30 Term of service by Commission members shall be three (3) years.

Article 31 (translation omitted)

Article 32 (translation omitted)

Article 33 (translation omitted)

Article 34 (translation omitted)

Article 35 (translation omitted)

(Specialist member)

Article 36

1. The Commission may appoint specialized member(s) to research and investigate matters of specialized area.
2. The specialized member(s) shall be chosen from experts and appointed by the Prime Minister.
3. The specialized members shall be removed from the Commission when the research/investigation regarding the subject matters is completed.
4. The specialized members shall be part-time.

(Secretariat)

Article 37

1. For the purpose of carrying out the work/duties of the Commission, a Secretariat office shall be established in the Commission.
2. The Secretary General and necessary staff shall be placed in the Secretariat office.
3. The Secretary General shall supervise and manage the duties of the Secretariat office by command of the Commission chairperson.

Article 38 Additional matters, as necessary, pertaining to the Commission shall be established by Cabinet Orders.

Supplemental Provisions

Article 1 – 7 (translation omitted)

Article 8 The Government, in consideration of changes in international standards and or opinions on measures regarding food safety assurance, as well as changes in social and economic situations, shall examine the status of enforcement of the legislation stipulated herein, and shall, as deemed necessary, take appropriate measures based on the result of the examination

Supplemental Resolutions

Upon enforcement of the legislation herein, the Government shall implement the appropriate measures, particularly on the following matters, in order to assure and reassure food safety.

1. In regard to “risk communication”, documents that serve as the basis for establishing various measures shall be widely distributed and sufficient consideration shall be given to allow for the constructive exchange of information and opinions between the related parties. constructive.
2. In regard to “traceability”, technical and economic research and studies shall be pursued. Based on the actual state and/or condition of food production and distribution, this system shall be promoted so that the tracking and tracing of food through the production and distribution process can be achieved.
3. Efforts shall be made to make the food safety regulations effective and practical.
4. From the perspective of assuring administrative transparency and providing information to public, Food Safety Commission meetings shall be open to public as a general principle, and reports on the status of its work shall be disclosed to public.
5. Consumer representative(s) shall be able to participate in the expert committee on planning and risk communication to be established within the Food Safety Commission.
6. Sufficient consideration shall be given to reflect opinions of consumers and food related businesses when making the annual plans for health impact assessments conducted by the Food Safety Commission.